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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,968	06/01/2001	Jack R. Wands	21486-047	3051

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EXAMINER

CROUCH, DEBORAH

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/872,968

Applicant(s)

WANDS ET AL.

Examiner

Deborah Crouch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, drawn to methods of inducing prolonged in vivo gene expression in mammal, classified in class 514, subclass 44.
- II. Claim 21-26 and 50-52, drawn to a nontransgenic model for Alzheimer's Disease comprising a nonhuman animal comprising an exogenous AD7c-NTP nucleic acid and methods of identifying a compound using the animal, classified class 800, subclass 12.
- III. Claims 27-32, drawn to a nontransgenic model for Alzheimer's Disease comprising a nonhuman animal comprising an exogenous NOS III nucleic acid, classified in class 800, subclass 12.
- IV. Claims 33 and 34, drawn to methods to inhibit Alzheimer's Disease associated neuronal cell death using AD7c-NTP antisense and a histone polypeptide, classified in class 514, subclass 44.
- V. Claims 35-39, 41-43 and 45, drawn to methods to inhibit Alzheimer's Disease associated neuronal cell death using an inhibitor of insulin, where the inhibitor is an antibody, classified in class 424, subclass 130.7.
- VI. Claims 35-39, 41-43 and 45, drawn to methods to inhibit Alzheimer's Disease associated neuronal cell death using an inhibitor of insulin, where the inhibitor is a polypeptide, classified in class 514, subclass 12.
- VII. Claims 35-39, 41-43 and 45, drawn to methods to inhibit Alzheimer's Disease associated neuronal cell death using an inhibitor of insulin, where the inhibitor is an organic molecule, classified in class 514.

- VIII. Claims 35-40,42 and 43, drawn to methods to inhibit Alzheimer's Disease associated neuronal cell death using an inhibitor of insulin like growth factor, where the inhibitor is an antibody, classified in class 424, subclass 130.7.
- IX. Claims 35-40,42 and 43, drawn to methods to inhibit Alzheimer's Disease associated neuronal cell death using an inhibitor of insulin like growth factor, where the inhibitor is a polypeptide, classified in class 514, subclass 12.
- X. Claims 35-40, 42 and 43, drawn to methods to inhibit Alzheimer's Disease associated neuronal cell death using an inhibitor of insulin like growth factor, where the inhibitor is an organic molecule, classified in class 514.
- XI. Claim 44, drawn to a method to inhibit Alzheimer's Disease associated neuronal cell death using an inhibitor of NOS III, not classifiable.
- XII. Claims 46-49, drawn to a method of identifying a compound which inhibits Alzheimer's Disease-associated neuronal cell death comprising contacting an AD7c-NTP over-expressing cell, classified in class 435, subclass 29.

The inventions are distinct, each from the other because:

Inventions I and II are mutually exclusive and independent. The in vivo method for prolonging expression in invention I is not required for the nontransgenic nonhuman model of Alzheimer's Disease comprising an exogenous AD7c-NTP nucleic acid in invention II, and vice versa.

Inventions I and III are mutually exclusive and independent. The in vivo method for prolonging expression in invention I is not required for the nontransgenic nonhuman model of Alzheimer's Disease comprising an exogenous NOS III nucleic acid in invention III, and vice versa.

Invention I and IV are mutually exclusive and independent. The in vivo method for prolonging expression in invention I is not needed for the method of inhibiting Alzheimer's Disease-associated neuronal cell death using AD7c-NTP antisense invention IV, and vice versa.

Inventions I and V are mutually exclusive and independent. The in vivo method for prolonging expression in invention I is not needed for the method of inhibiting Alzheimer's Disease-associated neuronal cell death using an antibody or antibody fragment inhibitor of insulin of invention V, and vice versa.

Inventions I and VI are mutually exclusive and independent. The in vivo method for prolonging expression in invention I is not needed for the method of inhibiting Alzheimer's Disease-associated neuronal cell death using a polypeptide inhibitor of insulin of invention VI, and vice versa.

Inventions I and VII are mutually exclusive and independent. The in vivo method for prolonging expression in invention I is not needed for the method of inhibiting Alzheimer's Disease-associated neuronal cell death using an organic molecule inhibitor of insulin of invention VI, and vice versa.

Inventions I and VIII are mutually exclusive and independent. The in vivo method for prolonging expression in invention I is not needed for the method of inhibiting Alzheimer's Disease-associated neuronal cell death using an antibody or antibody fragment inhibitor of insulin like growth factor of invention VIII, and vice versa.

Inventions I and IX are mutually exclusive and independent. The in vivo method for prolonging expression in invention I is not needed for the method of inhibiting Alzheimer's Disease-associated neuronal cell death using a polypeptide inhibitor of insulin like growth factor of invention IX, and vice versa.

Inventions I and X are mutually exclusive and independent. The in vivo method for prolonging expression in invention I is not needed for the method of inhibiting Alzheimer's Disease-associated neuronal cell death using an organic molecule inhibitor of insulin like growth factor of invention X, and vice versa.

Inventions I and XI are mutually exclusive and independent. The in vivo method for prolonging expression in invention I is not needed for the method of inhibiting Alzheimer's Disease-associated neuronal cell death comprising administering to an ADc7-NTP over expressing cells an inhibitor of NOS III of invention XI, and vice versa.

Inventions I and XII are mutually exclusive and independent. The in vivo method for prolonging expression in invention I is not needed for the method of identifying a compound that inhibits Alzheimer's Disease-associated neuronal cell death comprising contacting an ADc7-NTP over expressing cells a compound of invention XII, and vice versa.

Inventions II and III are mutually exclusive and independent. The nontransgenic animal model of invention II and that of invention III express materially different and separate nucleic acid sequence encoding proteins of no homologous sequence and separate biochemical function. Further, the model of invention II is not needed for the model of invention III and vice versa.

Inventions II and any one of IV-XI are mutually exclusive and independent. The nontransgenic animal model of invention II is not needed for any methods to inhibit Alzheimer's associated neuronal cell death of invention IV-XI, and vice versa.

Inventions II and XII are mutually exclusive and independent. The nontransgenic animal model of invention II is not needed for the method to identify compounds that inhibit Alzheimer's disease associated neuronal cell death in invention XII, and vice versa.

Inventions III and any one of IV-XI are mutually exclusive and independent. The nontransgenic animal model of invention III is not needed for any methods to inhibit Alzheimer's associated neuronal cell death of invention IV-XI, and vice versa.

Inventions III and XII are mutually exclusive and independent. The nontransgenic animal model of invention II is not needed for the method to identify compounds that inhibit Alzheimer's disease associated neuronal cell death of invention XII, and vice versa.

Inventions IV and inventions V-XI are mutually exclusive and independent. Invention IV uses an antisense molecule to ADc7-NTP and histone as the active agent. Inventions V-VII use antibodies, polypeptides and organic molecules to inhibit insulin. Inventions VIII-X use antibodies, polypeptides and organic molecules to inhibit insulin like growth factor. Invention XI uses an inhibitor of NOS III. Each of the active agents is materially different and separate as they are unrelated in design. Each active agent has a materially different mode of operation and target site. Further invention IV is not needed for the implementation of any of inventions V-XI, and vice versa.

Inventions IV and XII are mutually exclusive and independent. The method of inhibiting Alzheimer's Disease associated neuronal cell death of invention IV is not needed for the method to identify compounds that inhibit Alzheimer's disease associated neuronal cell death in invention XII, and vice versa.

Inventions V-XI are mutually exclusive and independent of each other. Inventions V-VII use antibodies, polypeptides and organic molecules to inhibit insulin. Inventions VIII-X use antibodies, polypeptides and organic molecules to inhibit insulin like growth factor. Invention XI uses an inhibitor of NOS III. Each of the active agents is materially different and separate as they are unrelated in design. Each active agent has a materially different mode of operation and target site. Further none of inventions V-XI are needed for the implementation of each other.

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Inventions V-XI and XII are mutually exclusive and independent. The methods of inhibiting Alzheimer's Disease associated neuronal cell death of inventions V-XI are not needed for the method to identify compounds that inhibit Alzheimer's disease associated neuronal cell death in invention XII, and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 703-308-1126. The examiner can normally be reached on M-Th and Tu-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.



Deborah Crouch, Ph.D.  
Primary Examiner  
Art Unit 1632

d. crouch  
May 25, 2002